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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,779	09/28/2007	Michael Teifel	40695.00600	9429

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MILBANK, TWEED, HADLEY & MCCLOY LLP
INTERNATIONAL SQUARE BUILDING
1850 K STRET, N.W., SUITE 1100
WASHINGTON, DC 20006

EXAMINER	
SCHULTZ, JAMES	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
09/06/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)
	10/575,779	TEIFEL ET AL.
	Examiner	Art Unit
	James D. (Doug) Schultz	1633

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 August 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *1* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *36-63 and 67-77*.
   Claim(s) withdrawn from consideration: *64-66*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/James D. (Doug) Schultz/
Primary Examiner, Art Unit 1633

Continuation of 3. NOTE: the limitation relating to the does for a single administration has not been presented or examined before, and its entry now after prosecution has been closed raises new issues that would require further consideration and/or search.

Continuation of 11. does NOT place the application in condition for allowance because:
Applicants arguments rely on evidence that could have been presented while prosecution was open but did not, and have failed to provide a showing of good and sufficient reasons why the evidence is necessary and was not earlier presented. In addition, applicants arguments rely on claim limitations that have been added after final, and for which entry has been refused. However in an attempt to promote compact prosecution, applicants arguments will be briefly addressed below.

Regarding the newly cited references provided after final, the fact that Ibrahim et al. (2002, Proc. Am. Soc. Clin. Oncol. 21 : Abstr 209); Bowden et al., (Proco Am Soco Clino Oncol. 2002, 21 :Abstr 1862); Treat et al, (Oncology 2001, 15, 44-48); and Soepenberg et al. (Euro J. Cancer, 40 (2004) 681-688) used higher doses than those claimed instantly is not relevant to the instant rejections, which do not rely on these references. While applicants appear to be attempting to summarize the state of the art, such a summary is simply diversionary in situations where the actual-cited references directly suggest the instantly claimed invention, which is considered to be true in the instant case.

Applicants argue that Rahman does not exemplify dosing ranges that overlap with those of the instant claims. This argument is not convincing, because Rahman, while not necessarily exemplifying the claimed dosing range, does in fact disclose ranges that overlap with the instantly claimed dosage range. The request for reconsideration repeatedly points to a lack of exemplification, particularly in regards to Rahman, in arguing that the teachings of Rahman should not be combined with those of McDonald. However, it is well established that exemplification is not required for a reference to be considered enabled in qualifying as prior art. Since Rahman discloses ranges that overlap with applicants presently claimed ranges, Rahman is considered to be properly relied upon.

Applicants argue that Rahman errs in stating that 50 to 300 mg/m2 of an active compound is equivalent to 0.5 to 5 mg/kilogram body weight of the active compound. This argument is not convincing for two reasons. First, the allegedly corrected range supplied by applicants (i.e. 1.28 to 7.7 mg/kg) still continues to overlap with applicants instantly claimed range (1.0 to 15 mg/kg per month, or .275 to 1.65 mg/kg per dose). The second is that Rahman (and by extension, the examiner) does not rely solely on this conversion as the critically-cited range. Rahman clearly teaches at the first full paragraph of column 4 that the preferable dosage is 1.0-3.0 mg/kg of active compound, still well within the presently claimed dosage range. It is not at all clear how differences between the teachings Rahman as actually cited presently (i.e. the '659 patent), and those of WO 00/01366, a reference which applicants assert is a later publication from the same inventor, and which has not been cited in any rejection in the instant case, somehow invalidate the disclosure of dosages of Rahman '659 as asserted by applicants. This argument appears to assume that a prohibition exists against changing parameters in related applications, a fact which has not been established by applicants and is not held to be true.

Applicants argue that cationic liposomes, which importantly, are also the presently claimed liposomal variety, are not appropriate for DNA or drug delivery based on a publication by Filion. However, a quick search of granted US patents for the term "cationic liposome" returns over 3700 hits. Furthermore a brief review of the references submitted in applicants IDS (e.g. Sharma et al., Campbell et al.) reveals titles like "Influence of Cationic Lipids on the Stability and Membrane Properties of Paclitaxel-Containing Liposomes", an article whose abstract concludes "Given the increased incorporation instability of paclitaxel in DOTAP-containing membranes and the potential for enhanced interaction with cells, cationic liposomes may provide a therapeutic advantage over previously described liposome formulations". Since thousands of issued US patents, applicants own data, as well as publications submitted by applicants in their Information Disclosure Statement all appear to agree, this argument is unconvincing.

As a point of clarification, while the rejection as originally stated refers to optimizing ranges as discussed in In re Aller, it is reiterated that the dosage range of the cited references actually overlaps strongly with the instantly claimed range. Thus, there really is no optimization required since the actual dosage conditions are disclosed in the prior art. The rejections should not be misconstrued as being reliant on the need to optimize since that process has already been disclosed in the prior art, for example by Rahman, who teaches preferable dosage ranges of 1.0-3.0 mg/kg.

Applicants have supplied a list of "technically related cases" that have not been considered, since they have not been provided in an information disclosure statement.

Finally, applicants understanding that the previous office action required the cancellation of nonelected species is incorrect. The actual text is as follows: "This application contains claims 64-66, John to an invention nonelected with traverse in the reply filed on January 18, 2011. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01." (Emphasis added). Applicants are again referred to the cited section of the MPEP to determine what other appropriate action might .